K120646

JUN - 7 2012

SPINEWAVE

510(k) Summary
CapSure® PS System

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
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Contact:	Roaida Rizkallah
Date Prepared:	June 4, 2012

2. Device Information

Trade Name:	CapSure® PS System
Common Name:	Pedicle Screw Spinal System
Classification Name:	Pedicle Screw Spinal System
Classification/ Code:	Class II per 21 CFR 888.3070 / MNH, MNI

3. Purpose of Submission

The purpose of this submission is to gain clearance for additional components for the CapSure® PS System, including hex-end titanium alloy and cobalt chrome alloy rods, additional screw sizes, and offset connectors. The indications for use is also being modified as a result of these line additions.

4. Predicate Device Information

The CapSure® PS System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
CapSure® PS System	Spine Wave, Inc.	K070245, K081228, K083353, K083743, K100122, and K111913
XIA® 3 System	Stryker Spine	K083393
USS System	Synthes	K111358

5. Device Description

The CapSure® PS System consists of a selection of non-sterile, single use, titanium alloy polyaxial screw and connector components, and titanium alloy and cobalt chrome alloy rod components that are assembled to create a rigid spinal construct. The components of the CapSure® PS System are attached to the non-cervical spine in order to stabilize the spine during fusion of the vertebral bodies, and are intended to be removed after spinal fusion is achieved.

6. Intended Use

The CapSure® PS System is a non-cervical spinal fixation system intended for posterior pedicle screw fixation (T1-S2/ilium) in skeletally mature patients. The CapSure® PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure® PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S2/ilium), and for whom the device is intended to be removed after solid fusion is attained.

7. Comparison of Technological Characteristics

The substantial equivalence of the subject CapSure® PS System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

Mechanical testing according to ASTM F1717, including static and dynamic compression bending and static torsion, were performed to demonstrate that the subject CapSure® PS System is substantially equivalent to the predicate CapSure® PS System.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the subject CapSure® PS System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Spine Wave, Inc.
% Ms. Roaida Rizkallah
Regulatory Affairs Manager
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K120646
Trade/Device Name: CapSure PS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: May 14, 2012
Received: May 15, 2012

Dear Ms. Rizkallah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120646

Indications for Use

510(k) Number (if known): K120646

Device Name: CapSure® PS System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) And / Or Over-The-Counter-Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120646

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